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Walker

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(54) **GRAFT FIXATION DEVICE**

(56) **References Cited**

(71) Applicant: **Peter Michael Sutherland Walker**,
Bellevue Hill (AU)

(72) Inventor: **Peter Michael Sutherland Walker**,
Bellevue Hill (AU)

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(21) Appl. No.: **13/921,208**

(22) Filed: **Jun. 19, 2013**

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(65) **Prior Publication Data**

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(30) **Foreign Application Priority Data**

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Primary Examiner — Suzette J Gherbi

(74) *Attorney, Agent, or Firm* — Clayton, Howarth &
Cannon, P.C.

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A61F 2/08 (2006.01)
A61B 17/04 (2006.01)

(57) **ABSTRACT**

(52) **U.S. Cl.**

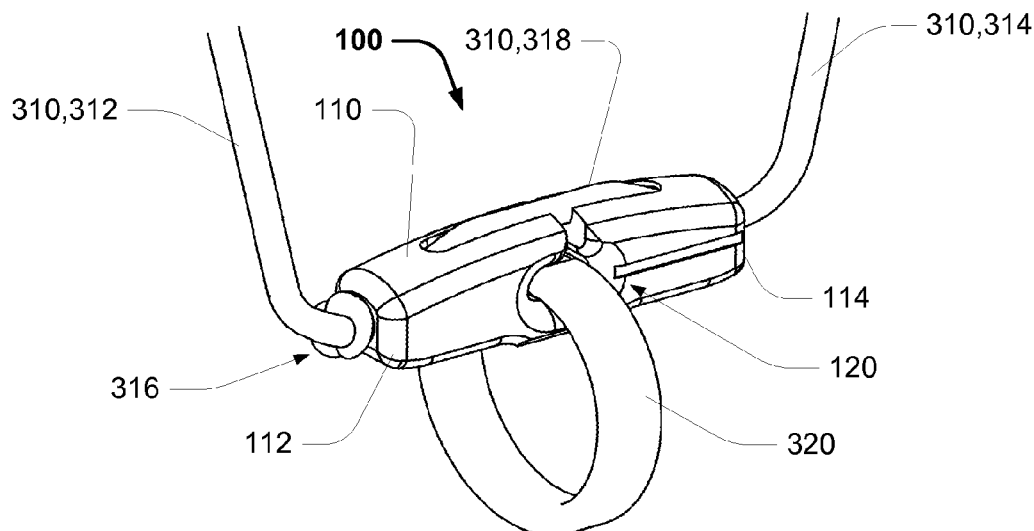
CPC **A61F 2/0811** (2013.01); **A61B 17/0401**
(2013.01); **A61B 2017/0414** (2013.01); **A61B**
2017/0417 (2013.01); **A61F 2002/0852**
(2013.01); **A61F 2002/0882** (2013.01)

A fixation device and method for retaining a graft. The device including: an elongate body having a first end and a second end; a transverse passage for retaining a graft retainer element; a first aperture located in the first end, and a second aperture in the second end; the first aperture and second aperture defining respective ends of a longitudinal through path. The method using the fixation device for drawing a graft through a first tunnel defined in a first bone and reining the graft when through.

(58) **Field of Classification Search**

CPC A61F 2/0811; A61F 17/04
USPC 623/13.11–13.15
See application file for complete search history.

24 Claims, 18 Drawing Sheets



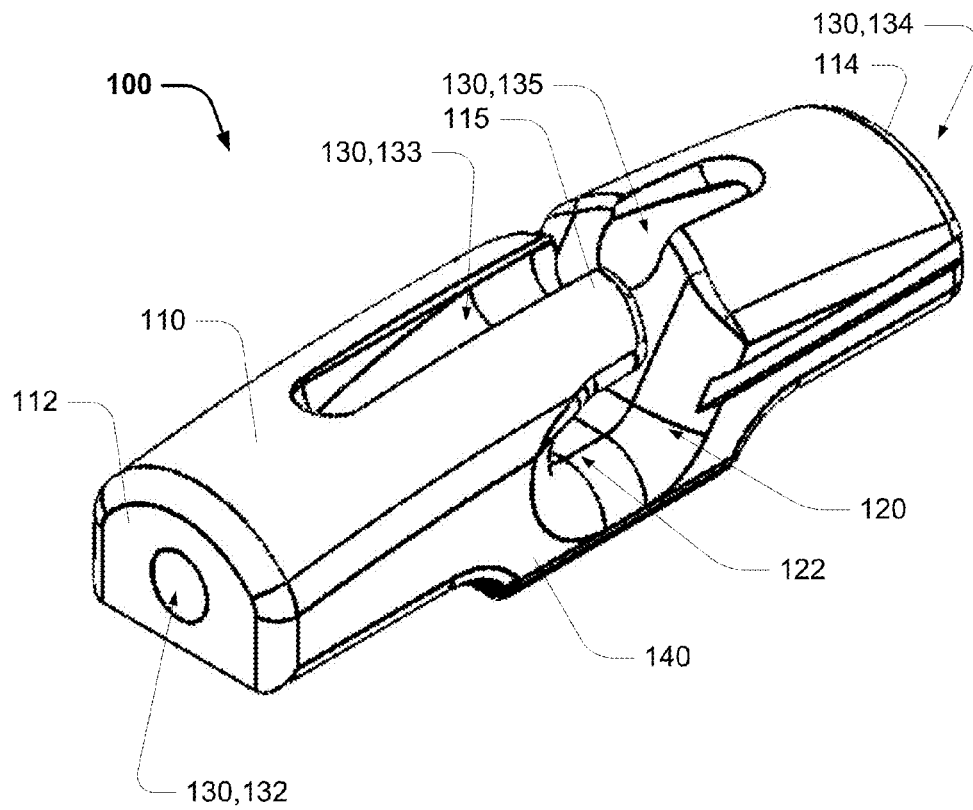


FIG. 1

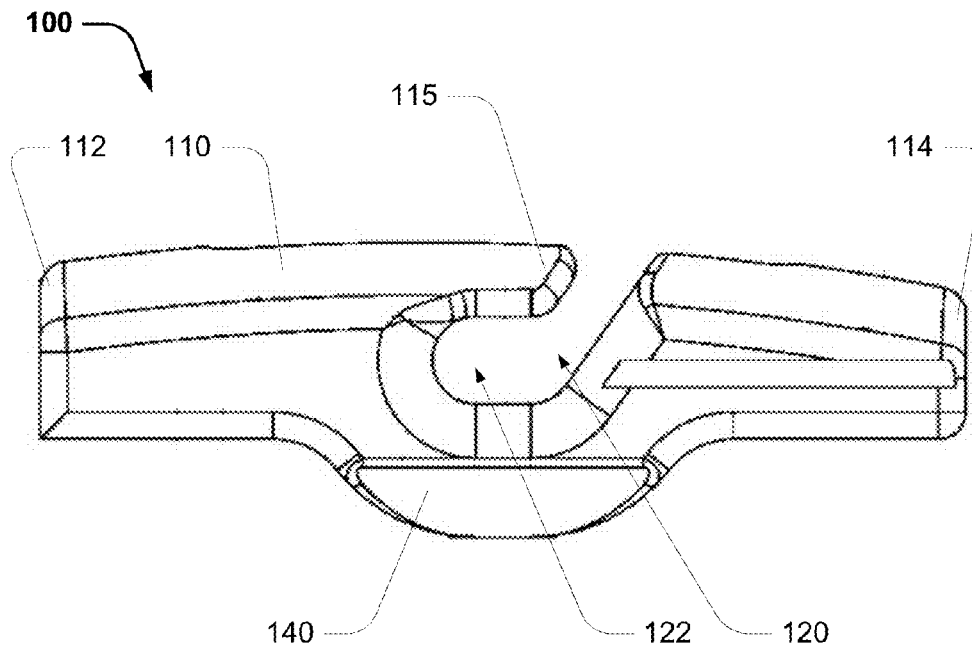


FIG. 2A

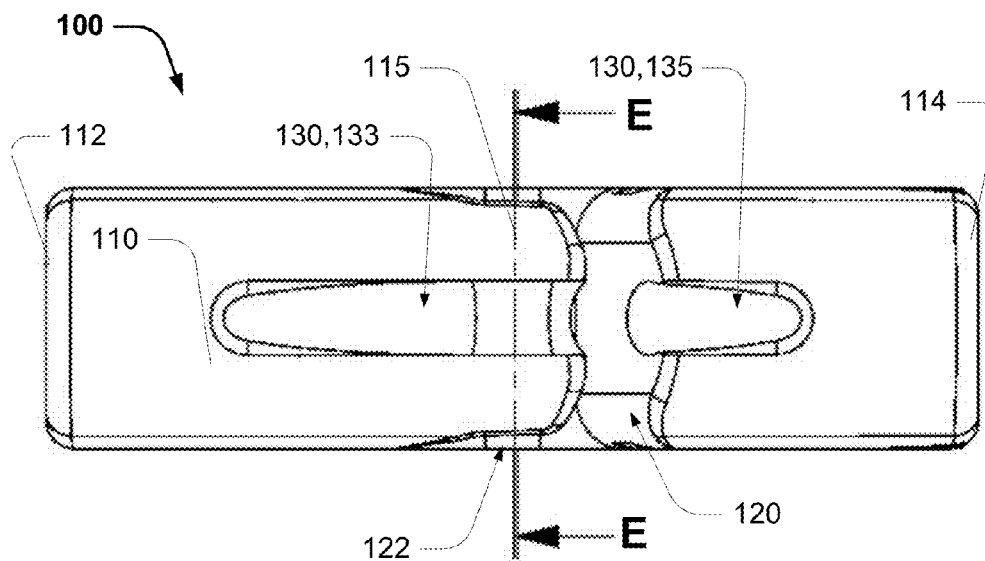


FIG. 2B

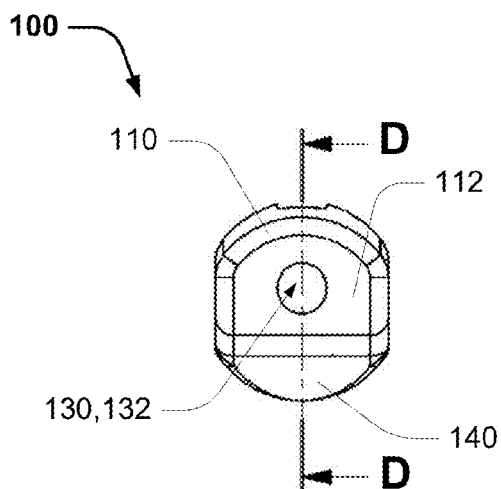


FIG. 2C

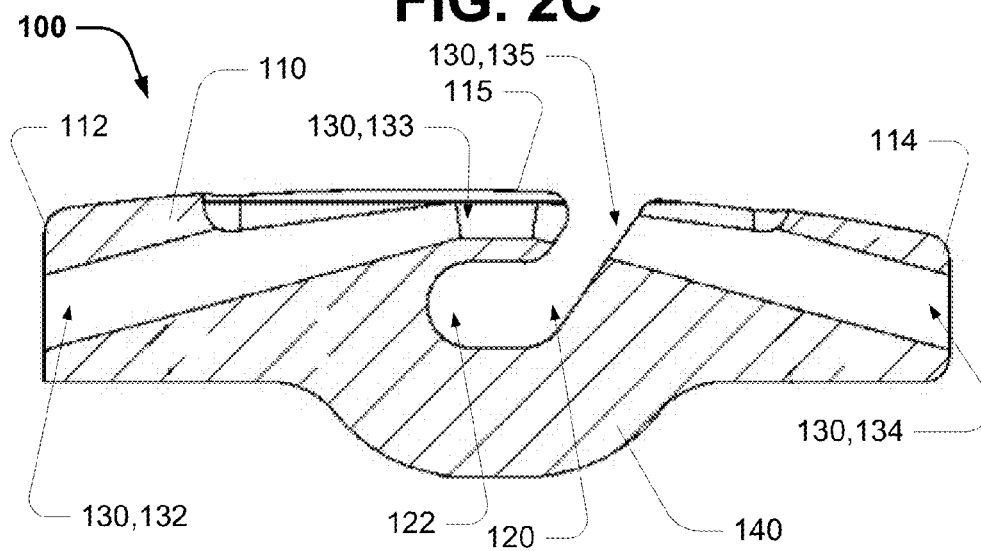


FIG. 2D

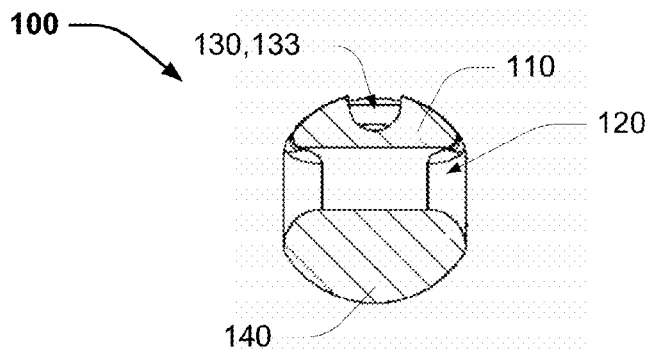


FIG. 2E

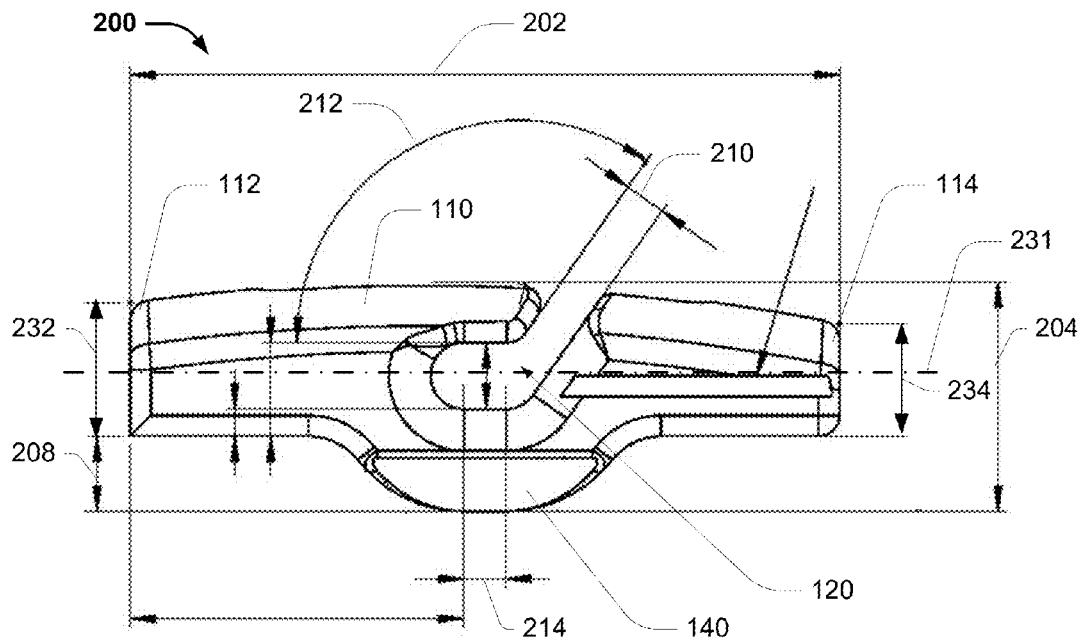


FIG. 3A

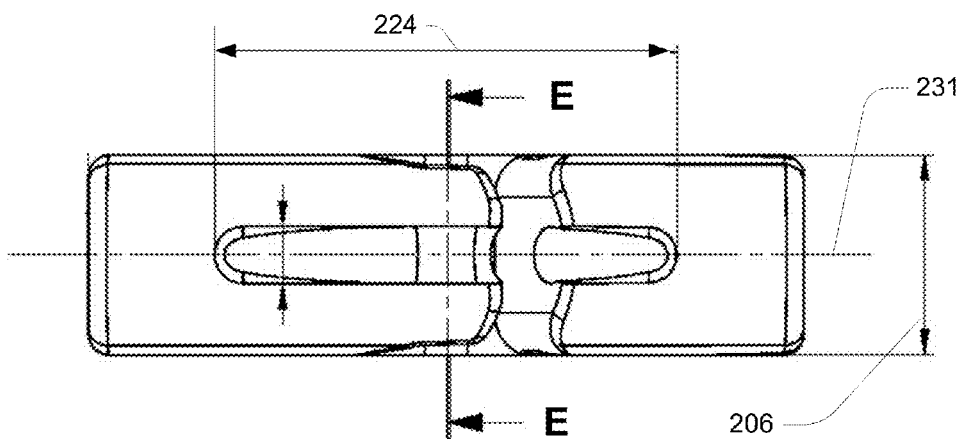


FIG. 3B

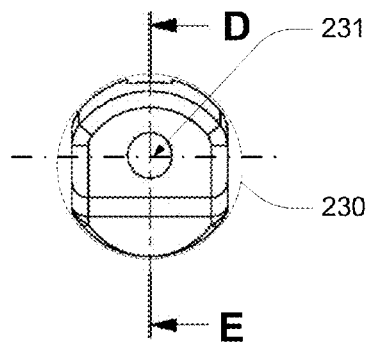


FIG. 3C

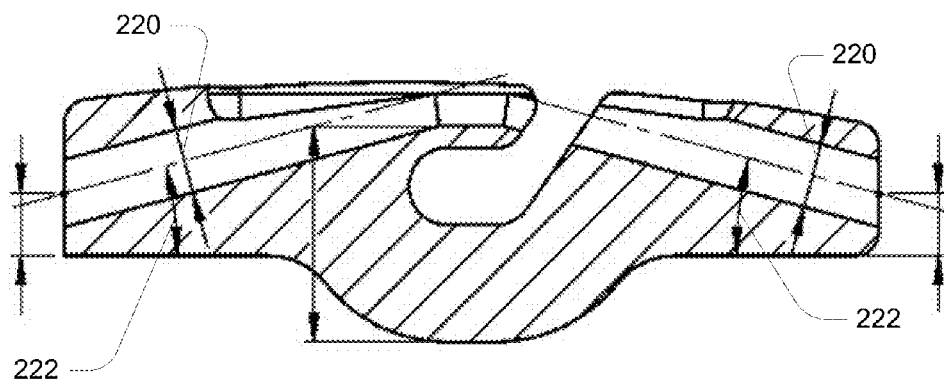


FIG. 3D

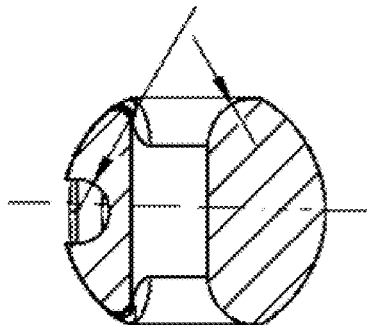


FIG. 3E

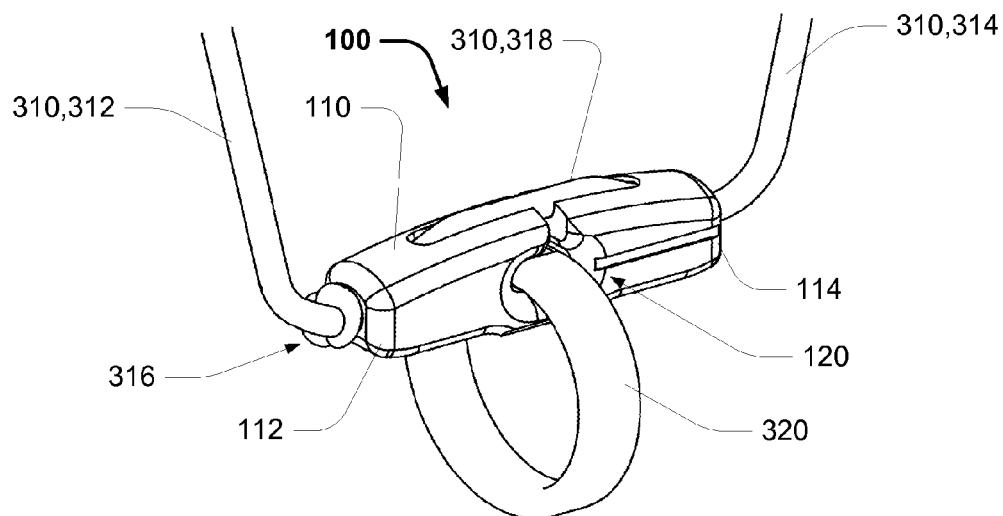


FIG. 4A

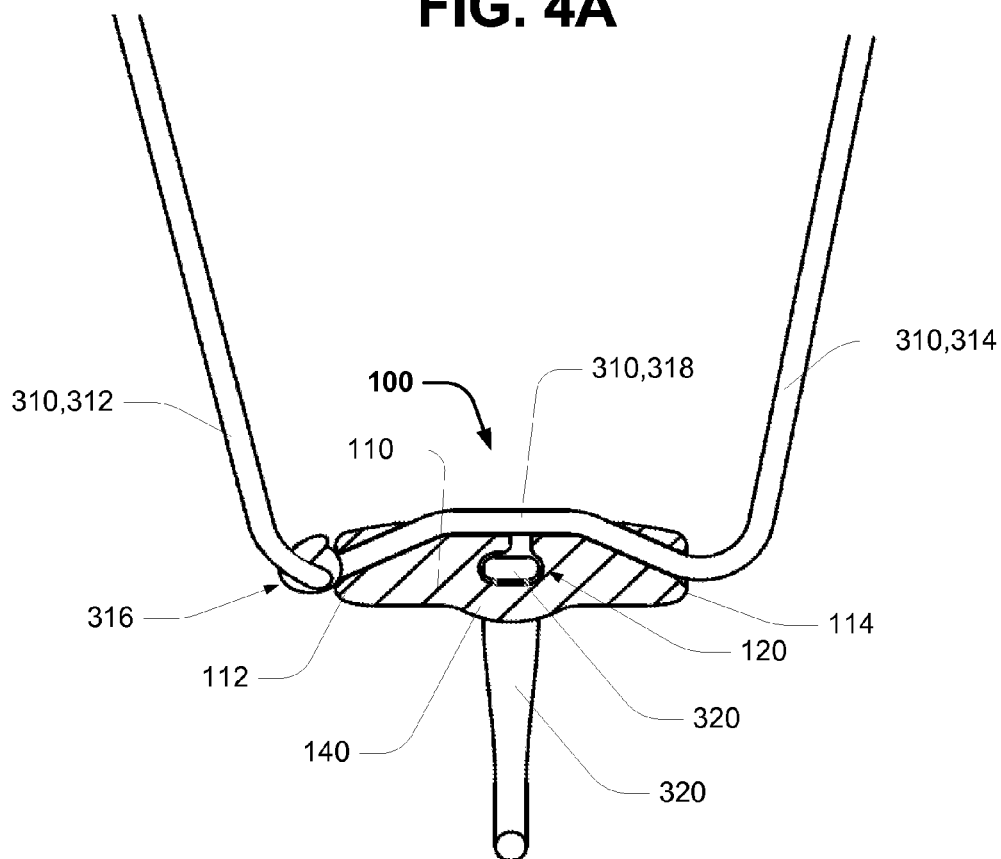


FIG. 4B

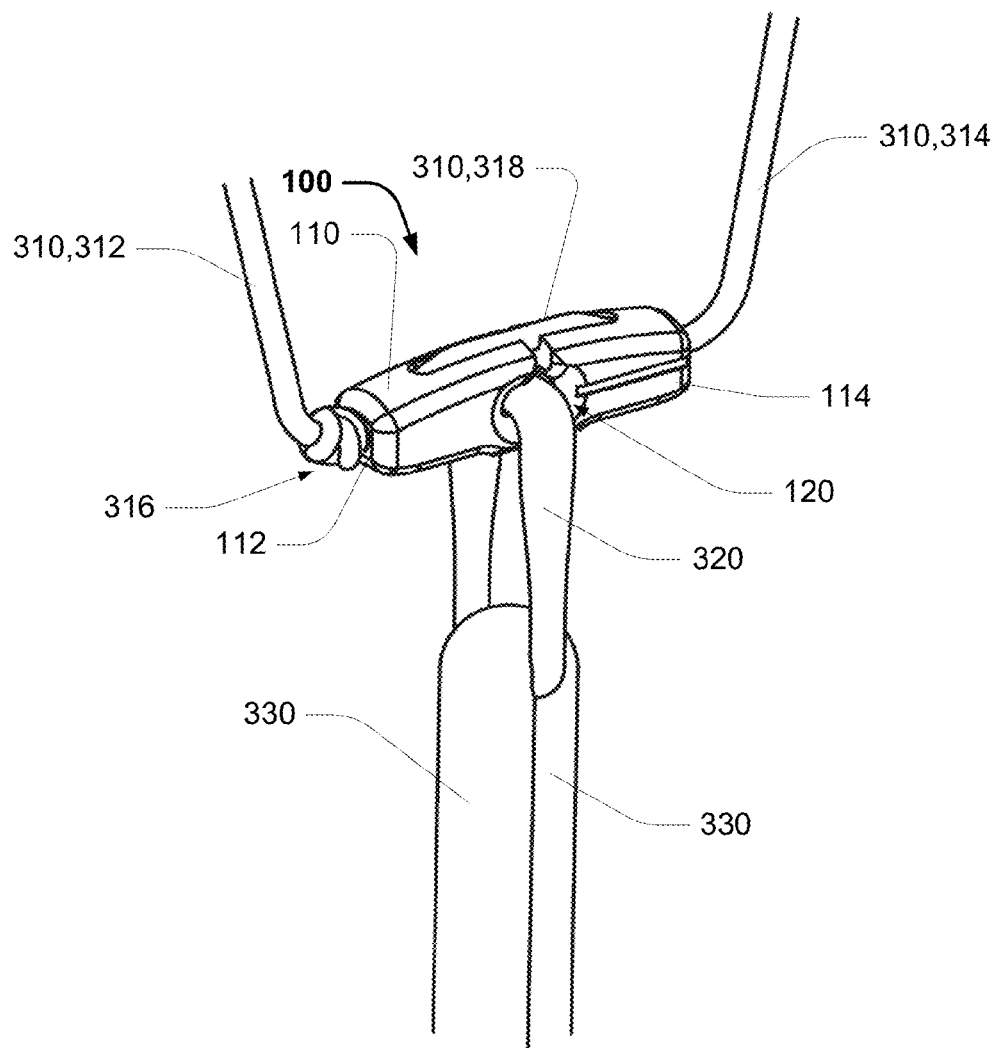


FIG. 4C

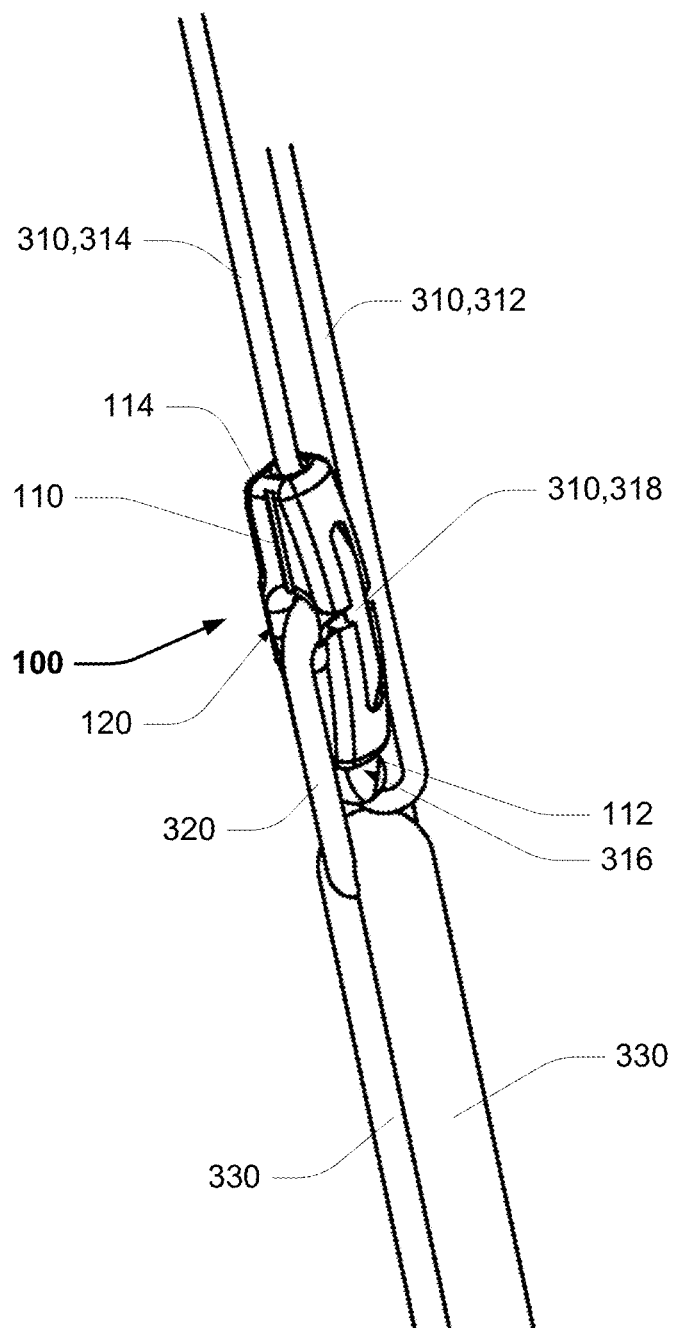


FIG. 4D

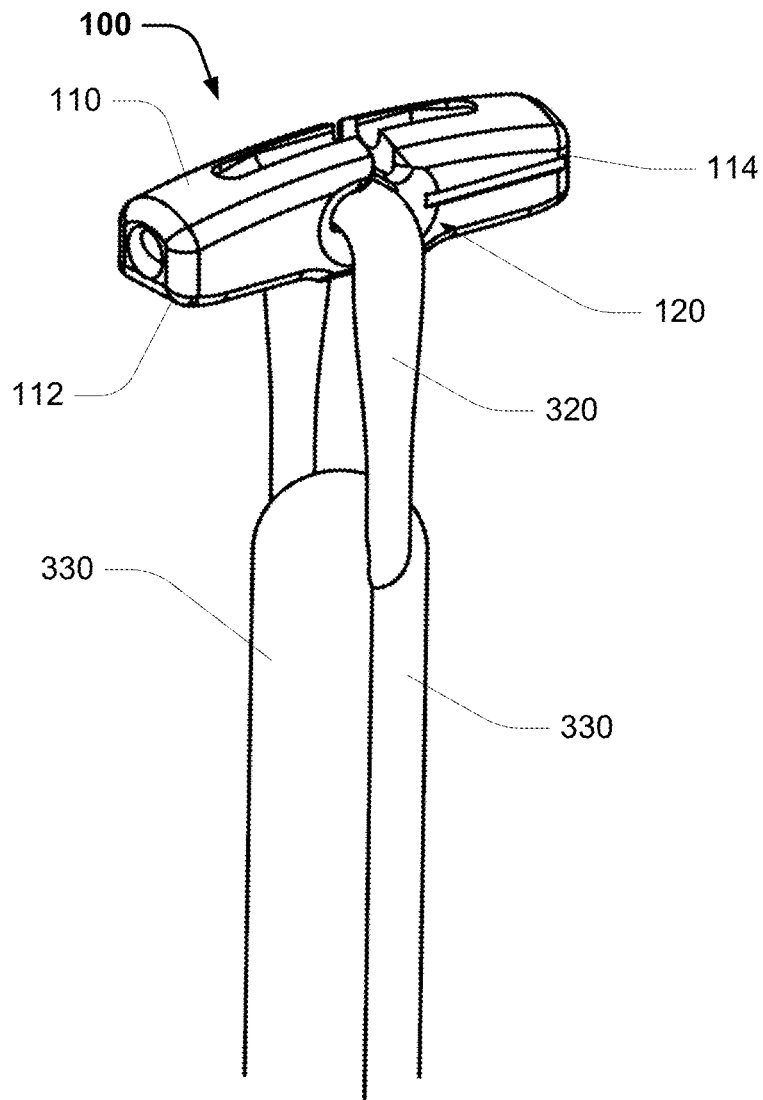


FIG. 4E

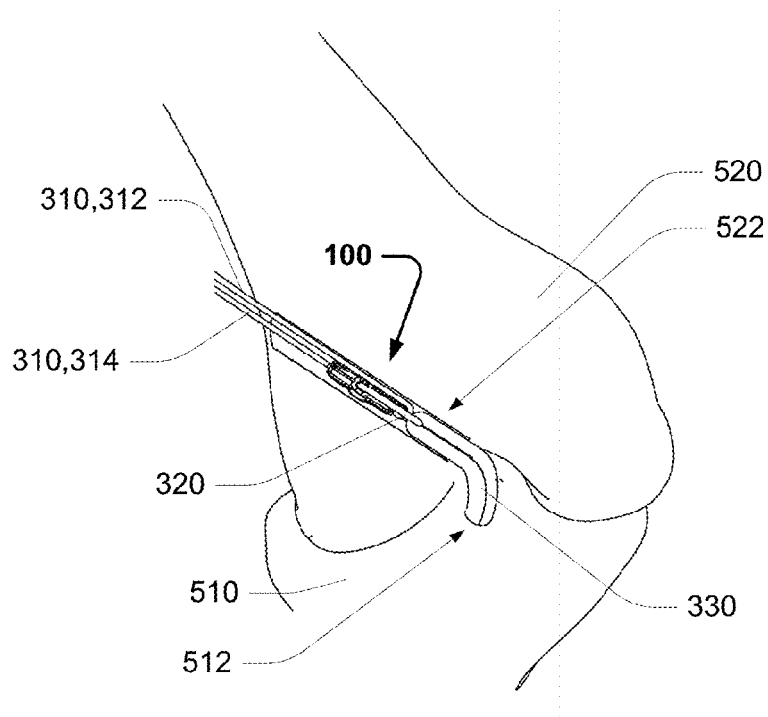


FIG. 5A

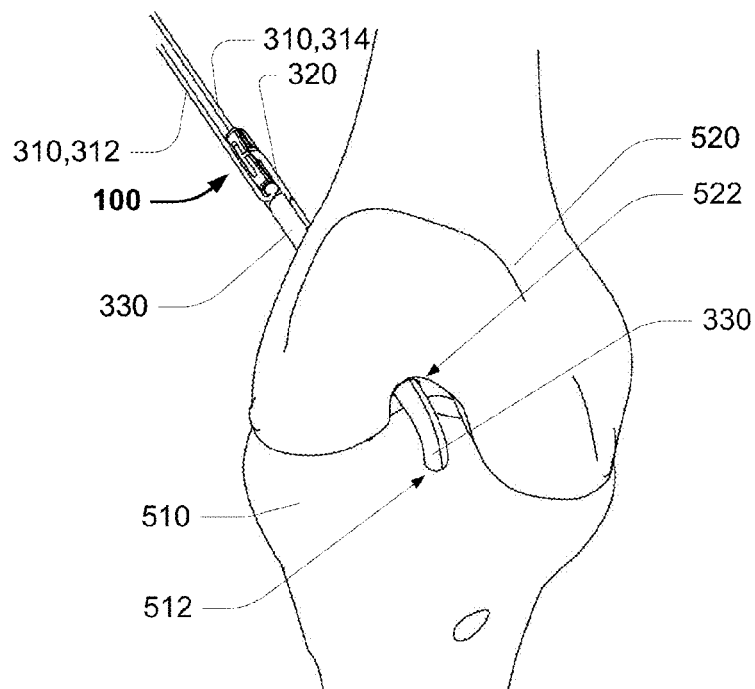


FIG. 5B

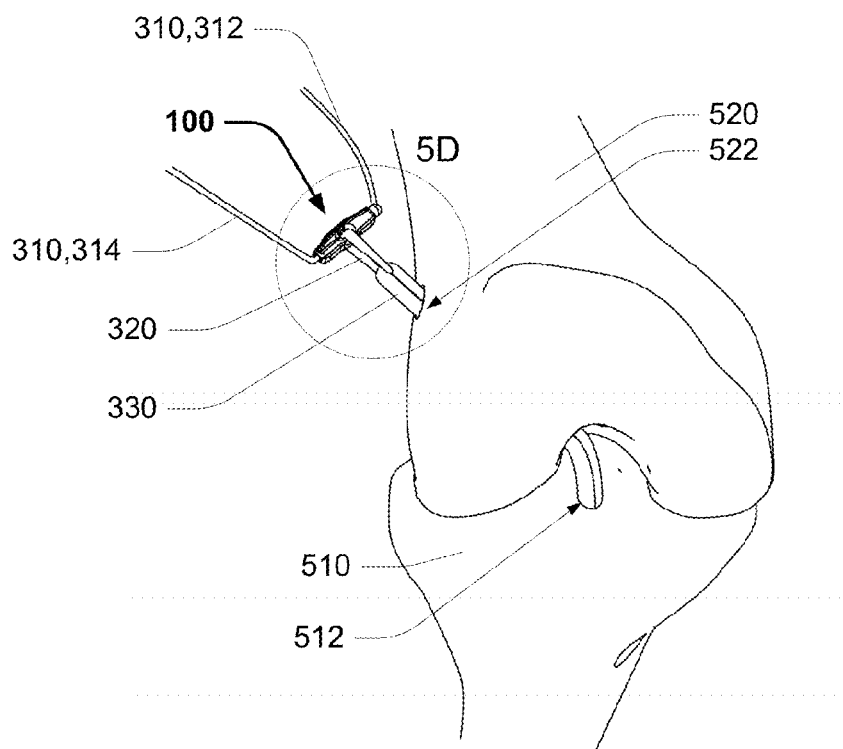


FIG. 5C

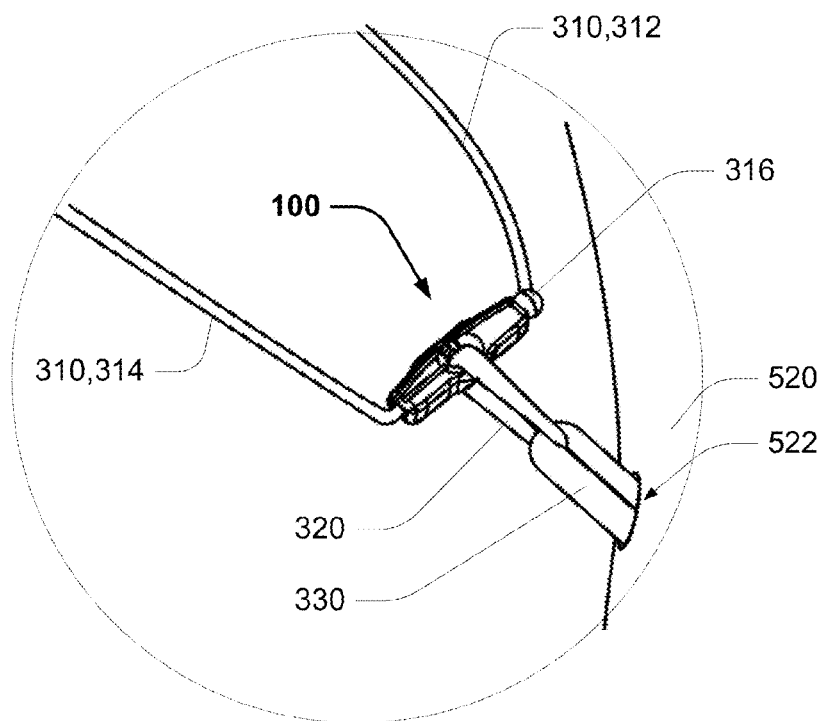


FIG. 5D

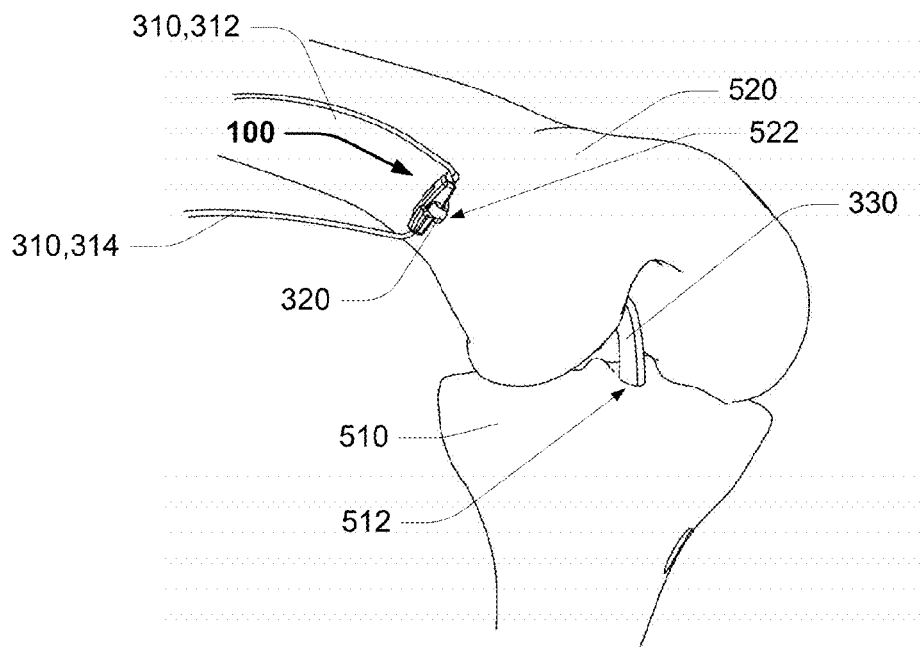


FIG. 5E

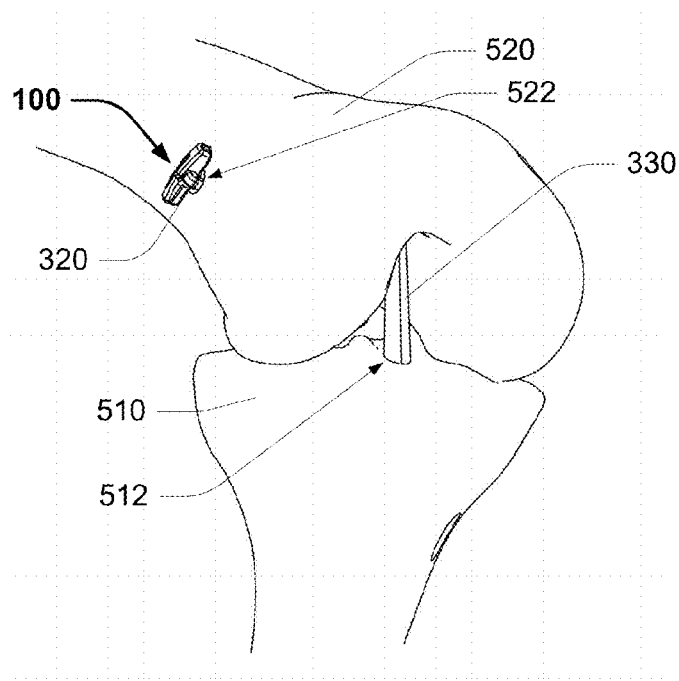
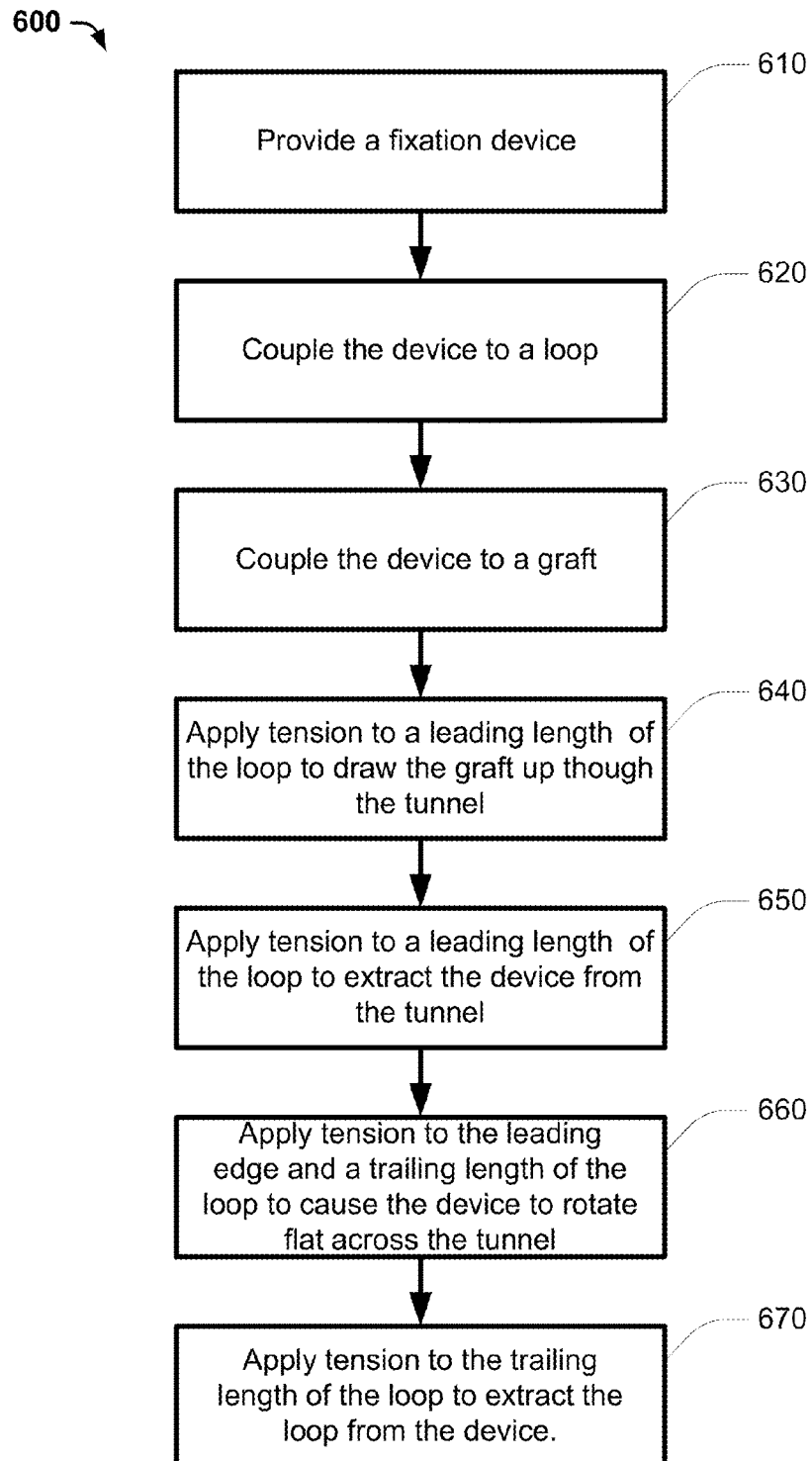


FIG. 5F

**FIG. 6**

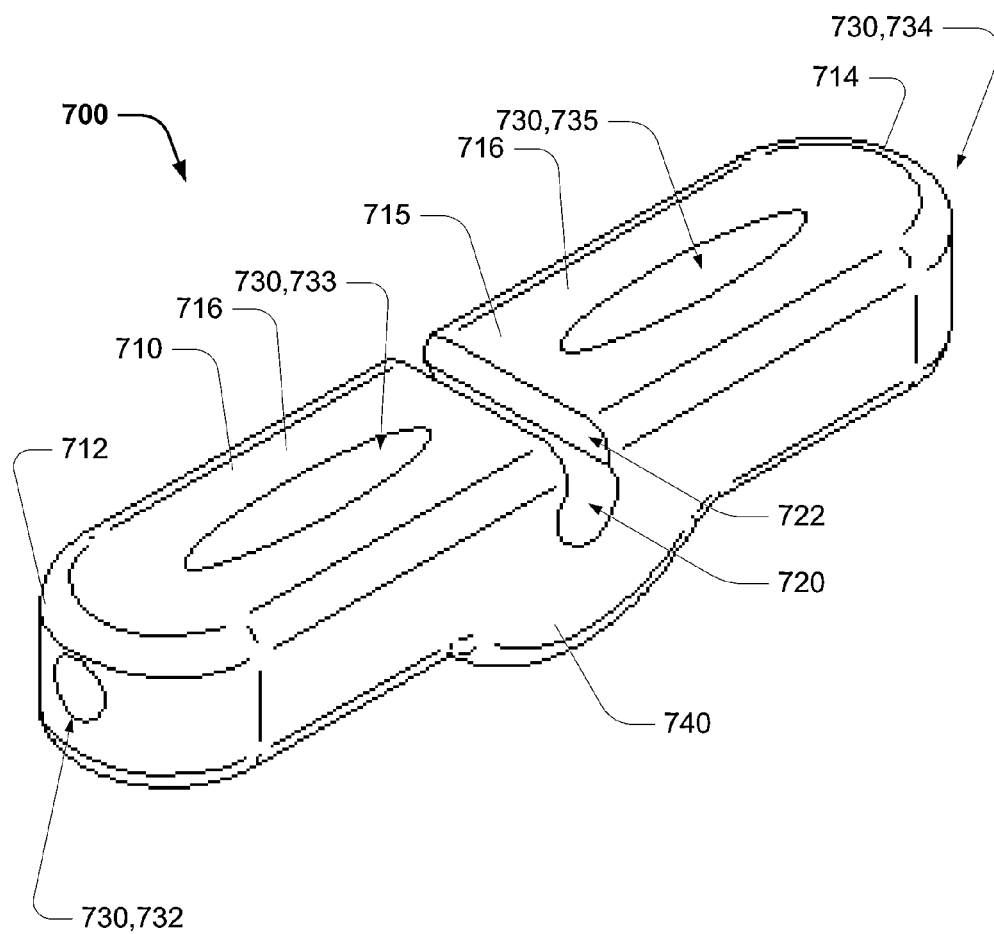


FIG. 7

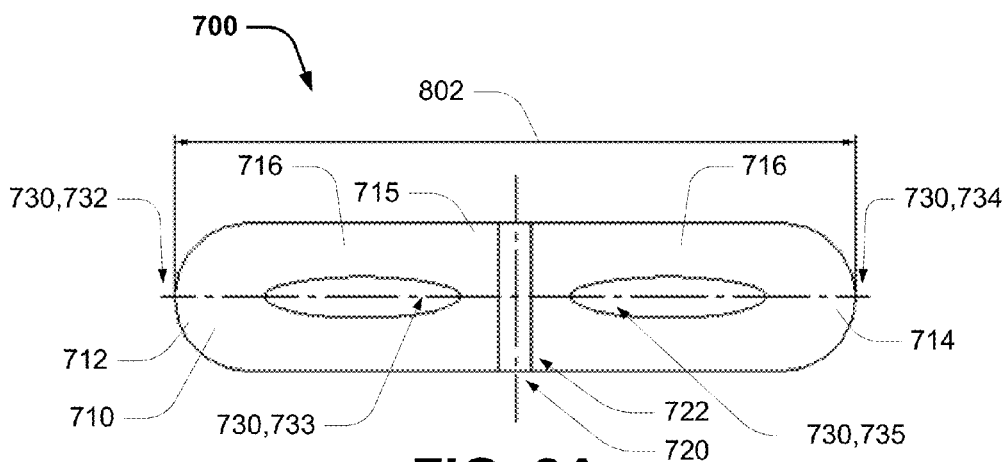


FIG. 8A

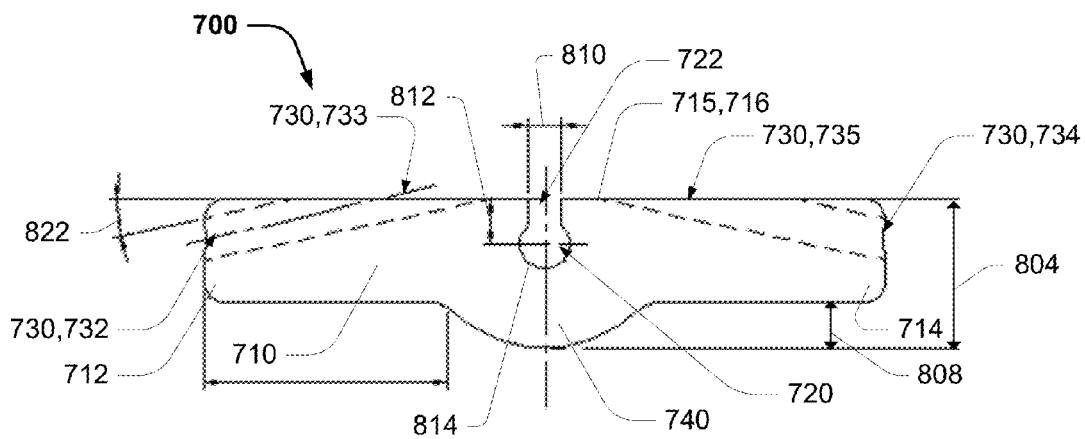


FIG. 8B

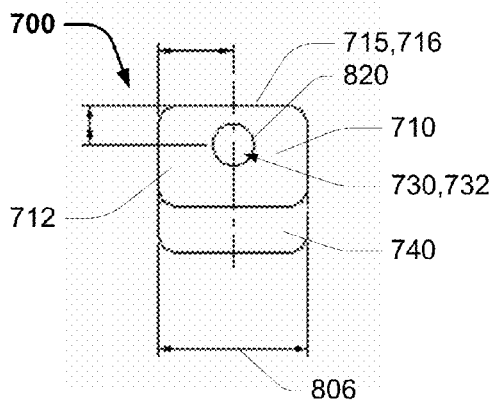


FIG. 8C

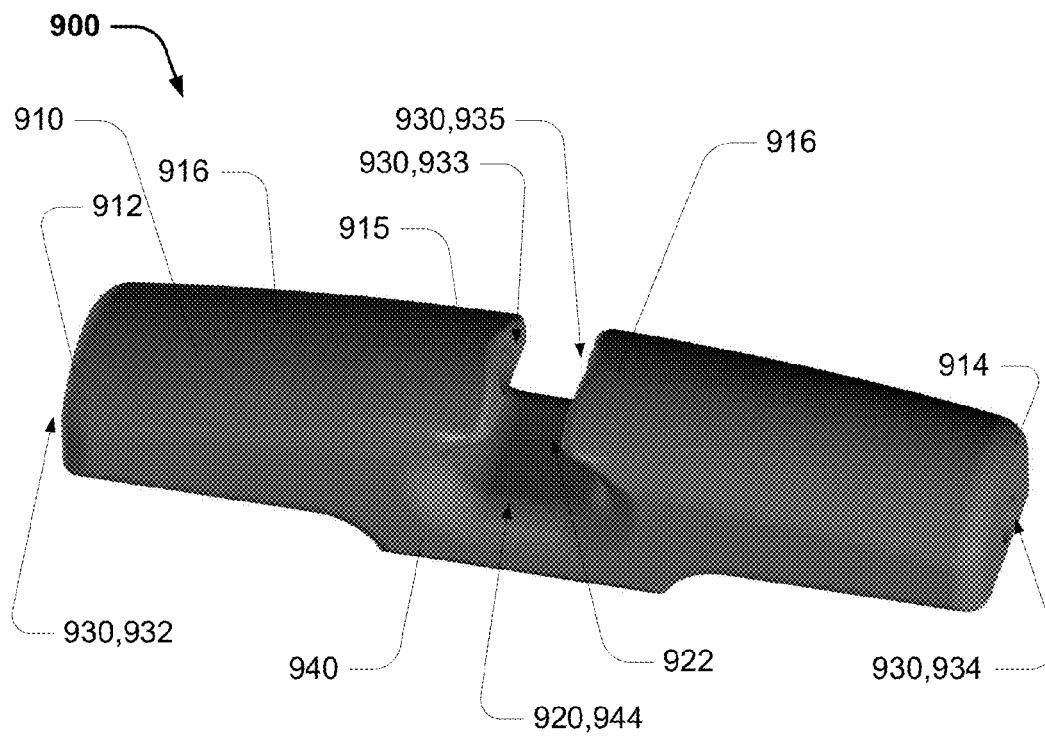


FIG. 9

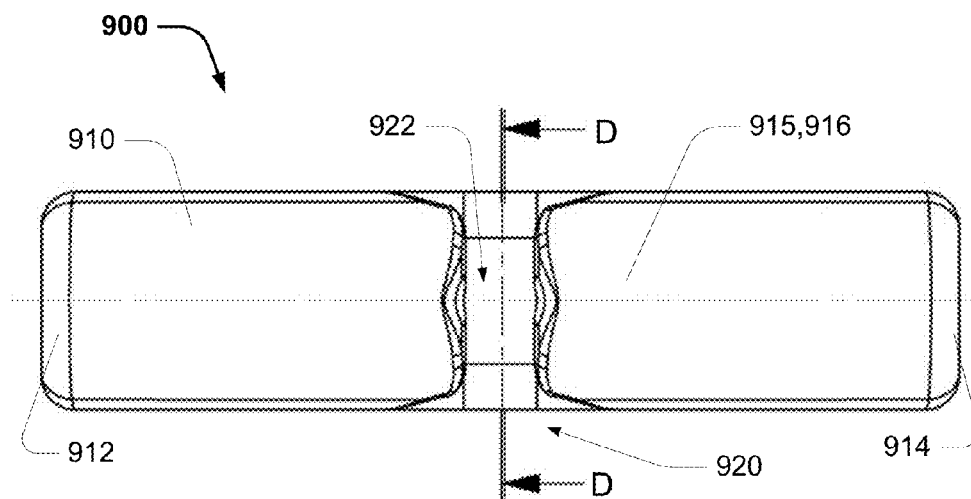


FIG. 10A

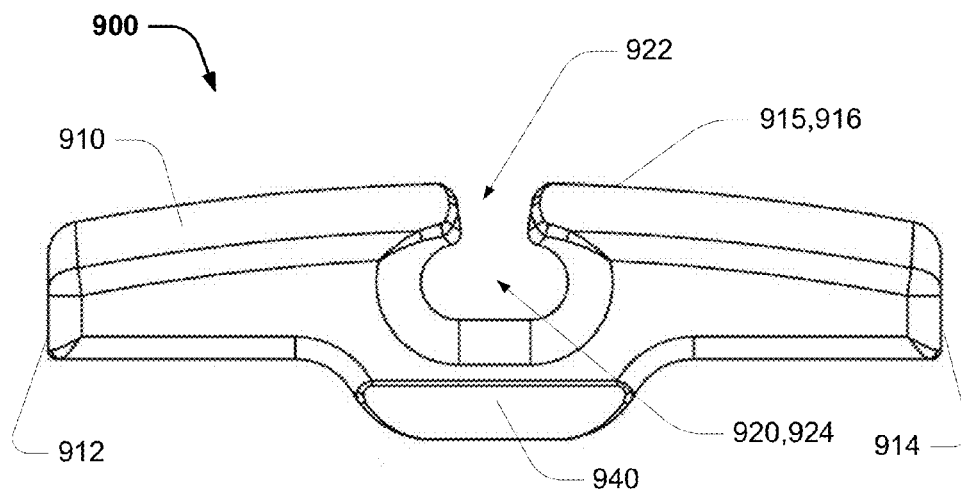


FIG. 10B

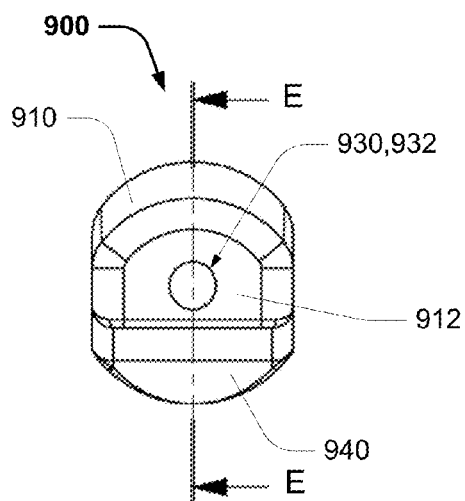


FIG. 10C

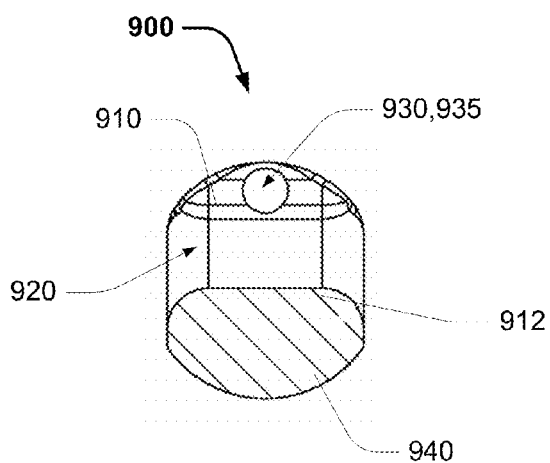


FIG. 10D

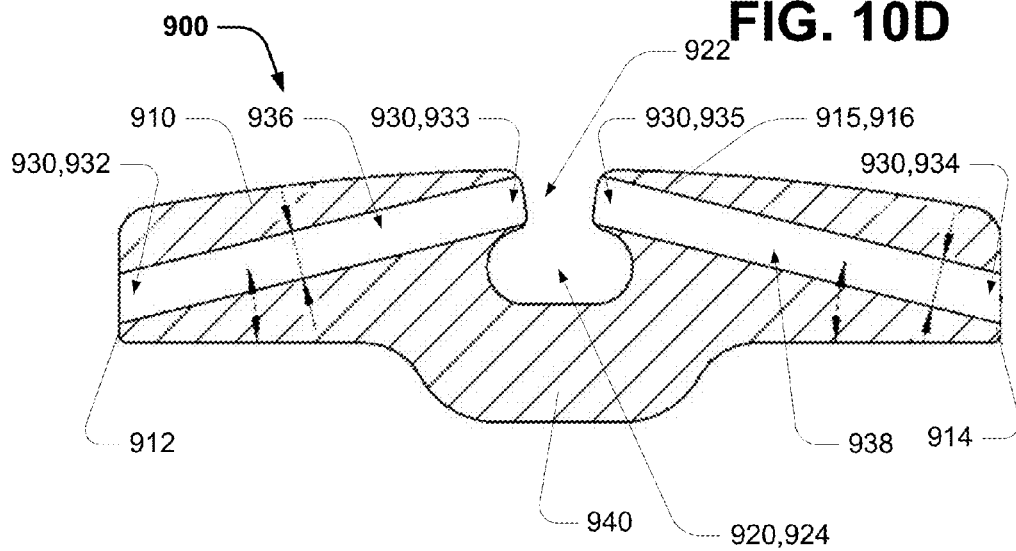


FIG. 10E

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GRAFT FIXATION DEVICE**FIELD OF THE INVENTION**

The present invention relates to retaining and fixation devices and in particular to devices for retaining or fastening grafts.

The invention has been developed primarily for use as a fixation device that can be used to retain or fasten a graft (including tendon or ligament) with respect to a bone and will be described hereinafter with reference to this application. However, it will be appreciated that the invention is not limited to this particular field of use.

BACKGROUND OF THE INVENTION

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of the common general knowledge in the field.

The present disclosure will be used with reference to an anterior cruciate ligament ("ACL") reconstruction, but it will be understood that the technology and methods of the present invention may have other applications for reconstruction of other parts of body

The ACL reconstruction can be performed in numerous ways. All common methods involve drilling holes or tunnels in the femur and tibia. These can be drilled using a variety of techniques. Grafts such as autografts, allografts or artificial biomaterials may be used to extend between the femoral tunnel and the tibial tunnel. The graft is then fixed to the appropriate bone structure, again numerous techniques being suitable. The replacement graft is fixed to the femur and tibia, most commonly by a screw into the adjacent bone, it being understood that staples, pins and similar devices may also be used.

A known device for retaining a graft proximal to the aperture to a femoral tunnel is an EndoButton™, as described in: U.S. Pat. No. 6,533,802 (issued 18 Mar. 2003). Similar devices are taught in U.S. Pat. No. 5,645,588 (issued 8 Jul. 1997) and U.S. Pat. No. 5,306,301 (issued 26 Apr. 1994).

The EndoButton™ includes an integrally formed continuous ring of polyester tape for fixation of soft tissue. The EndoButton can be drawn through the femoral tunnel through manipulation of a pair of suture loops each taken about and through one of respective pair of through apertures located at the ends of the device. When the device exits the through the femoral tunnel the pair of suture loops are manipulated to lay the device flat across the aperture to the femoral tunnel. Use of the EndoButton requires both pairs of suture loops to be manipulated and appropriately tensioned.

OBJECT OF THE INVENTION

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

It is an object of the invention in its preferred form to provide a graft fixation device for retaining graft located with a bone tunnel.

SUMMARY OF THE INVENTION

According to an aspect of the invention there is provided a graft fixation device comprising:
an elongate body having a first end and a second end;
a transverse passage for retaining a graft retainer element;

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a first aperture located in the first end, and a second aperture in the second end; the first aperture and second aperture defining respective ends of a longitudinal through passage.

Preferably, the body has a lower protruding portion located below the transverse passage. More preferably, the lower protruding portion is a smooth bulged portion that extends at least the longitudinal span of the transverse passage.

Preferably, the transverse passage is defined as a channel being open to an upper surface of the device. More preferably, a lower portion of the channel extends toward the first end. Most preferably, the channel has an hook or 'L' shaped profile. Alternatively, transverse through passage can be symmetric in profile.

Alternatively, the transverse through passage can be defined by a closed through aperture (being asymmetric or symmetric).

Preferably, the body tapers-down toward the second end; More preferably, the body tapers down toward the first end. Most preferably, the body tapers down from a central region toward both the first end and second end.

Preferably, the graft retainer element is a closed loop element adapted to be located in the transverse passage for retaining the graft with respect to the device. More preferably, the loop is a continuous woven material. Alternatively, the loop is integrally formed with an artificial graft.

Preferably, the first aperture and the second aperture is located proximal to the centre of the respective first end and second end. Preferably, the longitudinal through passage is sized to receive a length of suture.

Preferably, the longitudinal through passage extends from the first aperture to a first intermediate aperture proximal to the transverse passage, and from a second intermediate aperture proximal to the transverse passage to the second aperture. More preferably, the longitudinal through passage is intersected by the transverse passage. Most preferably, the longitudinal through passage is defined by a first passage segment and a second passage segment, each passage segment being substantially straight inwardly-upwardly through-passages extending from a respective first end and second end. Alternatively, the longitudinal through passage can be axially directed.

According to an aspect of the invention there is provided a method of using a fixation device for drawing a graft through a first tunnel defined in a first bone, the method comprising the steps of:

- (a) providing a fixation device;
- (b) coupling the fixation device to a loop having a stop abutting a first end of the fixation device;
- (c) coupling the fixation device to a first end of the graft;
- (d) applying tension to a leading length of the loop to cause the fixation device to draw the graft up through the tunnel;
- (e) applying tension to a leading length of the loop to cause the fixation device to exit the tunnel;
- (f) applying tension to the leading edge and a trailing length of the loop to cause the fixation device to rotate flat across the tunnel; and
- (g) applying tension to the trailing length of the loop to thereby extract the loop from the fixation device.

According to an aspect of the invention there is provided a method of using a fixation device for drawing a graft through a first tunnel defined in a first bone, the method comprising the steps of:

- (a) providing a fixation device;
- (b) coupling the fixation device to a length of suture having a stop abutting a first end of the fixation device;

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- (c) coupling the fixation device to a first end of the graft;
- (d) applying tension to a leading portion of the length of suture to cause the fixation device to draw the graft up through the tunnel;
- (e) applying tension to a leading portion of the length of suture to cause the fixation device to exit the tunnel;
- (f) applying tension to the leading edge and a trailing portion of the length of suture to cause the fixation device to rotate flat across the tunnel; and
- (g) applying tension to the trailing portion of the length of suture to thereby extract the length of suture from the fixation device.

Preferably, the device is used during knee surgery when replacing a tendon or ligament.

Preferably, the graft is a ligament or tendon being either a transplant or artificial.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

FIG. 1 is a perspective view of an embodiment fixation device according to the invention;

FIG. 2A is a side view of the device of FIG. 1;

FIG. 2B is a plan view of the device of FIG. 1;

FIG. 2C is an end view of the device of FIG. 1;

FIG. 2D is a sectional side view of the device taken along line D-D of FIG. 2C;

FIG. 2E is a sectional end view of the device taken along line E-E of FIG. 2B;

FIG. 3A is a side view of an embodiment fixation device according to the invention;

FIG. 3B is a plan view of the device of FIG. 3A;

FIG. 3C is an end view of the device of FIG. 3A;

FIG. 3D is a sectional side view of the device taken along line D-D of FIG. 3C;

FIG. 3E is a sectional end view of the device taken along line E-E of FIG. 3B;

FIG. 4A is a perspective view of an embodiment fixation device according to the invention, shown configured with a suture loop and a graft fixation loop;

FIG. 4B is a sectional side view of the device of FIG. 4A;

FIG. 4C is a perspective view of the device of FIG. 4A, shown with a joined graft;

FIG. 4D is a perspective view of the device of FIG. 4C, shown in a configuration for drawing through a femoral tunnel;

FIG. 4E is a perspective view of the device of FIG. 4C, shown with the suture loop removed;

FIG. 5A-5F are perspective views illustrating steps involved in utilisation of the invention in conjunction with an ACL reconstruction; and

FIG. 6 shows a flowchart for an embodiment method of using a fixation device according to the invention;

FIG. 7 is a perspective view of an embodiment fixation device according to the invention;

FIG. 8A is a side view of the device of FIG. 7;

FIG. 8B is a plan view of the device of FIG. 7;

FIG. 8C is an end view of the device of FIG. 7;

FIG. 9 is a perspective view of an embodiment fixation device according to the invention;

FIG. 10A is a plan view of the device of FIG. 9;

FIG. 10B is a side view of the device of FIG. 9;

FIG. 10C is an end view of the device of FIG. 9;

FIG. 10D is a sectional end view of the device taken along line D-D of FIG. 10A; and

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FIG. 10E is a sectional side view of the device taken along line E-E of FIG. 10C.

PREFERRED EMBODIMENT OF THE INVENTION

Referring initially to FIG. 1 of the drawings, and FIG. 2A to FIG. 2E, an embodiment fixation device **100**, by way of example only, can comprise:

- an elongate body **110** having a first end **112** and a second end **114**;

- a transverse passage **120** for retaining a graft retainer element (not shown);

- a longitudinal through passage **130** having a first aperture **132** located in the first end, and a second aperture **134** in the second end.

The first aperture **132** and second aperture **134** define respective ends of the transverse passage **130**. The longitudinal through passage is typically sized to receive a length of suture. Typically, the first aperture and the second aperture can be located proximal to the centre of the respective first end and second end.

By way of example only, the longitudinal through passage **130** extends from the first aperture **132** to a first intermediate aperture **133** proximal to the transverse passage, and from a second intermediate aperture **135** proximal to the transverse passage to the second aperture **134**. In this embodiment, the longitudinal through passage is intersected by the transverse passage. As best shown in FIG. 2D, the longitudinal through passage **130** is defined by a first passage segment **136** and a second passage segment **138**, wherein the first passage segment is a substantially straight inwardly-upwardly through-passage extending from the first end **112**, and wherein the second passage segment is a substantially straight inwardly-upwardly through-passage extending from the second end **114**. It will be appreciated that, the longitudinal through passage can be defined in a plurality of configurations wherein the passage comprises a first aperture **132** and a second aperture **134** defined proximal to respective ends of the device. For example, in an embodiment, the longitudinal through passage can be axially directed.

In this embodiment, the body has a lower protruding portion **140** located below the transverse passage **120**. The lower protruding portion is defined by a smooth bulged portion that extends at least the longitudinal span of the transverse passage. It will be appreciated that the protuberance can provide longitudinal rigidity across the transverse passage, and can assist in locating the device about the tibial through passage.

In accordance with the present example embodiment, the transverse passage **120** can be defined as a channel that is open to an upper surface of the device. The lower portion of the channel can extend (referring to reference **122**) toward the first end. It will be appreciated that, by way of example only, the channel can be an angled slot, or have a hook or 'L' shaped profile. Alternatively, a transverse through passage can be defined a closed through aperture—wherein a graft retainer element is manufactured in situ with the device. An open channel can be necked down to resist release of an inserted graft retainer element.

The body tapers down from a central region **115** toward both the first end **112** and second end **114**. This can assist movement of the device through a bone tunnel.

The graft retainer element is typically, but not limited to, a closed loop element adapted to be located within the transverse passage. By way of example, the graft retainer element can be a loop of continuous woven material.

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The graft retainer element can be used for retaining the graft with respect to the device, or alternatively can be a loop that is integrally formed with an artificial graft. It will be appreciated that, by having an open channel, a closed loop can be located after manufacture of the device. Alternatively, the loop can be manufactured in situ (or integrally formed with) the device.

By way of example, a graft retainer element can be a loop of fibre material (for example suture material), which can be placed over (or through) the transverse passage. The graft can then be retained by passing it through the loop.

It will be appreciated that the device can be used during knee surgery for fixation of a graft, wherein the graft can include a ligament or tendon being either a transplant or artificial. All references to a graft includes a transplant or artificial tendon and/or ligament.

By way of example an artificial graft can be combined from multiple artificial tendon strands that are braided to form a graft retainer element in situ.

It is noted that edges of the device have been rounded to avoid sharp edges, for example: about the exterior of the device; and about or within the passages.

In an embodiment, by way of an example only, a fixation device **200** can have dimensions as defined with reference to FIG. 3A through FIG. 3E.

Accordingly, referring to FIG. 3A through FIG. 3E, a fixation device **200** can have:

- an overall length **202** of about 20 mm;
- an overall height **204** of about 5.5 mm;
- an overall width **206** of about 5.5 mm;
- a lower protruding portion height **208** of about 1.8 mm;
- a transverse passage having a slot width **210** of about 1 mm
- an inclination **212** of about 125 degrees; a lower portion of the passage extends **214** about 1 mm having a height **216** of about 1.6 mm, having a concave terminus having a radius **218** of about 0.8 mm;
- a longitudinal through passage having nominal bore diameter **220** of about 1.35 mm, a first passage segment and a second passage segment each inclined **222** at about 15 degrees; an intermediate open segment of the passage extending **224** about 1 mm; and
- the body has an overall diameter **230**, about the longitudinal axis **231**, of about 5.5 mm; and the body tapers down from a central toward both the first end having a height **332** of about 3.2 mm and second end having a height **234** of about 2.7 mm.

Depending on the size of the device (thereby imparting a structural strength) and the intended use of the device, it will be appreciated that the device can be manufactured from materials including (but not limited to) any one or more of the materials selected from the set comprising: metals (such as titanium), metal alloys (such as stainless steels, cobalt-chromium alloys, and titanium alloys), metal composites, ceramics, polymers or plastics (such as polyethylene) and carbon fibre.

FIG. 4A through FIG. 4E show an embodiment fixation device **100** configured for retaining a graft.

In this configuration, a length of suture material **310** is threaded through the device to define a loop having a trailing length **312** and a leading length **314**. The suture material loop having a stop **316** which abuts the first end **112** of the fixation device. In this embodiment, the stop **316** is a knot formed at an intermediate position of the suture material **310**. It will be appreciated that the stop can be associated with the suture material **310**, including any one of the following methods selected from the set: applied to, integrally formed with, interconnected with, or attached to.

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In this configuration a graft retainer element **320** is located within (and retained by) the transverse passage **120**. The graft retainer element is by way of example only a loop graft retainer element. By way of example, a graft **330** can be passed through the loop graft retainer element and doubled back—as shown in FIG. 4C.

It will be appreciated that a portion **318** of the length of suture material **310**, extends across the transverse passage **120** and over the graft retainer element **320**—as shown in FIG. 4B. This reduces the risk that the graft retainer element **320** can be dislodged, particularly while tension is maintained on the leading length **314**.

In use, by applying tension to a leading length **314** of the suture loop **310**, the fixation device **100** can be drawn end on in the direction of the leading edge—as shown in FIG. 4D. By applying tension to the trailing length **314** of the suture loop **310**, the device can be rotated flat, and the suture loop can be extracted from the device—as shown in FIG. 4E.

FIG. 5A through FIG. 5F show method steps for using an embodiment fixation device (for example fixation device **100**) configured for retaining a graft during an anterior cruciate ligament (“ACL”) reconstruction.

FIG. 5A through FIG. 5F shows the femur **510** and tibia **520** are first drilled to form a femoral tunnel **512** and tibial tunnel **522** respectively. In this example, it is noted that the femoral tunnel **512** and tibial tunnel **522** can have a single diameter (typically about 7-10 mm in diameter) throughout their respective length.

Upon providing a fixation device **100**; a first end of the graft **330** is coupled to the fixation device, for example using a graft retainer element **320**; and a loop (for example a loop of suture material **310**) is coupling the fixation device **100**, wherein a stop **316** on the loop abutting a first end of the fixation device.

FIG. 5A shows tension applied to a leading length **314** of the loop causes the fixation device to draw the graft up through the tunnel.

FIG. 5B shows tension applied to a leading length **314** of the loop to cause the fixation device to exit the tunnel **522**.

FIG. 5C, FIG. 5D and FIG. 5E shows that, by applying tension to the leading edge **314** and a trailing length **312** of the loop, the fixation device **100** is rotated flat across the tunnel **522**.

FIG. 5F shows that by applying tension to the trailing length **312** of the loop enables extraction of the loop **310** from the fixation device **100**, leaving the fixation device located proximal to and across the tunnel **522**—thereby to retain the graft relative to the fixation device and the bone.

It will be appreciated that by locating the second aperture (e.g. **134**) on the second end **114**, and by applying tension to the leading length **314** of the suture loop, the device is drawn through the tunnel in an end-on configuration (e.g. as shown in

FIG. 4D and FIG. 5A). Typically the second aperture is located on the second end of the device proximal to a central longitudinal axis. Travel of the device through the bone tunnel is substantial parallel to the central longitudinal axis. It will be further appreciated that this preferred trajectory can be enhanced by locating the first aperture (e.g. **132**) on the second end of the device proximal to a central longitudinal axis.

It will be appreciated that reference to a suture loop represents a preferred element, and can alternatively comprise any strand element or filament element being suitable for medical procedures and having sufficient length and strength to draw the device in use through a bone tunnel.

An embodiment method **600**, depicted in FIG. 6, is taught for using a fixation device **100** for drawing a graft **330** through

a first tunnel (e.g. **522**) defined in a first bone (e.g. **520**). The method comprising the steps of:

- STEP **610**: providing a fixation device **100**;
- STEP **620**: coupling the fixation device **100** to a loop (for example a loop of suture material **310**) having a stop **316** abutting a first end of the fixation device;
- STEP **630**: coupling the fixation device to a first end of the graft **330**, for example using a graft retainer element **320**;
- STEP **640**: applying tension to a leading length **314** of the loop to cause the fixation device to draw the graft up through the tunnel—as shown in FIG. **5A**;
- STEP **650**: applying tension to a leading length **314** of the loop to cause the fixation device to exit the tunnel **522**—as shown in FIG. **5B**;
- STEP **660**: applying tension to the leading edge **314** and a trailing length **312** of the loop to cause the fixation device **100** to rotate flat across the tunnel **522**—as shown in FIG. **5C**, FIG. **5D** and FIG. **5E**; and
- STEP **670**: applying tension to the trailing length **312** of the loop to thereby extract the loop **310** from the fixation device **100**, as shown in FIG. **5F**.

A suture is used pulls the device up the tunnel using a knot or expansion at abutting the device. Once the graft is in place the surgeon can keep tension on the suture and rotate/flip the device so it is sitting transversely across a bone aperture. The suture can then be removed by pulling it in the opposite direction.

It will be appreciated by those skilled in the art that other embodied may have many other forms.

Referring to FIG. **7** and FIG. **8A** through FIG. **8C**, by way of example only, an embodiment fixation device can have the form **700**. In this embodiment, the fixation device **700**, comprises:

- an elongate body **710** having a first end **712** and a second end **714**;
- a transverse passage **720** for retaining a graft retainer element (not shown);
- a longitudinal through passage **730** having a first aperture **732** located in the first end, and a second aperture **734** in the second end.

The first aperture **732** and second aperture **734** defines respective ends of the transverse passage **730** that is not fully enclosed. Typically, the first aperture and the second aperture can be located proximal to the centre of the respective first end and second end.

By way of example only, the longitudinal through passage **730** extends from the first aperture **732** to a first intermediate aperture **733** proximal to the transverse passage **720**, and from a second intermediate aperture **735** proximal to the transverse passage **720** to the second aperture **734**. In this embodiment, the longitudinal through passage exits at the first intermediate aperture **733** and the second intermediate aperture **733** located on the upper surface **716** of the device.

As best shown in FIG. **8B**, the longitudinal through passage **730** is defined by a first passage segment **736** and a second passage segment **738**, wherein the first passage segment is a substantially straight inwardly-upwardly through-passage extending from the first end **712**, and wherein the second passage segment is a substantially straight inwardly-upwardly through-passage extending from the second end **714**.

It will be appreciated that, the longitudinal through passage can be defined in a plurality of configurations wherein the passage comprises a first aperture **732** and a second aperture **734** defined proximal to respective ends of the device. For example, in an embodiment, the longitudinal through passage can be axially directed.

In this example, the transverse passage **722** is necked down to resist release of an inserted graft retainer element (not shown).

Referring to FIG. **8A** through FIG. **8C**, the fixation device **700** can have:

- an overall length **802** of about 20 mm;
- an overall height **804** of about 5 mm;
- an overall width **206** of about 5 mm;
- a lower protruding portion height **208** of about 1.5 mm;
- a transverse passage having a necked slot width **810** of about 1 mm; a depth **812** of about 1.5 mm; wherein a lower portion of the passage having a diameter **814** of about 1.6 mm;
- a longitudinal through passage having nominal bore diameter **820** of about 1.2 mm, a first passage segment and a second passage segment each inclined **822** at about 12 degrees.

In this example embodiment, in plan view (e.g. FIG. **8A**) the body **710** is rectangular having fully rounded edges.

Referring to FIG. **9** and FIG. **10A** through FIG. **10E**, by way of example only, an embodiment fixation device can have the form **900**. In this embodiment, the fixation device **900**, comprises:

- an elongate body **910** having a first end **912** and a second end **914**;
- a transverse passage **920** for retaining a graft retainer element (not shown);
- a longitudinal through passage **930** having a first aperture **932** located in the first end, and a second aperture **934** in the second end.

The first aperture **932** and second aperture **934** defines respective ends of the transverse passage **930** that is not fully enclosed. Typically, the first aperture and the second aperture can be located proximal to the centre of the respective first end and second end.

By way of example only, the longitudinal through passage **930** extends from the first aperture **932** to a first intermediate aperture **933** proximal to the transverse passage **920**, and from a second intermediate aperture **935** proximal to the transverse passage **920** to the second aperture **934**. In this embodiment, the longitudinal through passage exits at the first intermediate aperture **933** and the second intermediate aperture **933** located in cavity defined by the transverse passage **920** of the device.

As best shown in FIG. **10E**, the longitudinal through passage **930** is defined by a first passage segment **936** and a second passage segment **938**, wherein the first passage segment is a substantially straight inwardly-upwardly through-passage extending from the first end **912**, and wherein the second passage segment is a substantially straight inwardly-upwardly through-passage extending from the second end **914**. In this embodiment, each passage segment **936**, **938** is inwardly-upwardly directed at an angle of 12 to 15 degrees, and having a bore diameter of about 1 mm.

In this example embodiment, the first passage segment and the second passage segment of the longitudinal through passage have an aperture located within the surface defining the transverse passage.

It will be appreciated that, the longitudinal through passage can be defined in a plurality of configurations wherein the passage comprises a first aperture **932** and a second aperture **934** defined proximal to respective ends of the device. For example, in an embodiment, the longitudinal through passage can be axially directed.

In this example, the transverse passage **920** is necked down **922** to define a substantially oval passage **924** for resisting release of an inserted graft retainer element (not shown). It

will ne appreciated that the substantially oval profile **924** of the transverse passage **920** enables the graft retainer to move toward one end when the device is drawn end-on though a bone passage.

In this example embodiment, in plan view (e.g. FIG. 8A) the body **910** is rectangular having fully rounded edges, and a convex upper surface. It will be appreciated that the edges and corners of the device are curved to minimise risk of the device cutting or gouging, or becoming caught or snagged during use.

It will be appreciated that the illustrated device can retain a graft located with a bone tunnel. The graft is a ligament or tendon being either a transplant or artificial. The device can be used during surgery (in particular knee surgery) when replacing a tendon or ligament.

It will be further appreciated that by including a the transverse passage that is symmetric and slightly longitudinally extended, for example such that is necked down to define a more oval passage, it reduces the risk that of incorrect orientation (e.g. longitudinal-direction) of the device during use—and which enables the stop (or knot) to be proximal to either end during preliminary configuration of the device.

It will be further appreciated that the device may be sided (i.e. a smaller version), such that during use a smaller tunnel is first drilled through the outer femoral cortex and then a larger tunnel is drilled not all the way through the cortex. This configuration can be (but is not limited to) a substantially similar length to the previously disclosed devices (for example about 12 mm) but having an overall diameter of about 4.5 mm.

Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

Reference throughout this specification to “one embodiment” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases “in one embodiment” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

In the claims below and the description herein, any one of the terms comprising, comprised of or which comprises is an open term that means including at least the elements/features that follow, but not excluding others. Thus, the term comprising, when used in the claims, should not be interpreted as being limitative to the means or elements or steps listed thereafter. For example, the scope of the expression a device comprising A and B should not be limited to devices consisting only of elements A and B. Any one of the terms including or which includes or that includes as used herein is also an open term that also means including at least the elements/features that follow the term, but not excluding others. Thus, including is synonymous with and means comprising.

Similarly, it is to be noticed that the term coupled, when used in the claims, should not be interpreted as being limitative to direct connections only. The terms “coupled” and “connected”, along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Thus, the scope of the expression a device A coupled to a device B should not be limited to devices or systems wherein an output of device A is directly connected to an input of device B. It means that there exists a

path between an output of A and an input of B which may be a path including other devices or means. “Coupled” may mean that two or more elements are either in direct physical, or that two or more elements are not in direct contact with each other but yet still co-operate or interact with each other.

As used herein, unless otherwise specified the use of the ordinal adjectives “first”, “second”, “third”, etc., to describe a common object, merely indicate that different instances of like objects are being referred to, and are not intended to imply that the objects so described must be in a given sequence, either temporally, spatially, in ranking, or in any other manner.

As used herein, unless otherwise specified the use of terms “horizontal”, “vertical”, “left”, “right”, “up” and “down”, as well as adjectival and adverbial derivatives thereof (e.g., “horizontally”, “rightwardly”, “upwardly”, etc.), simply refer to the orientation of the illustrated structure as the particular drawing figure faces the reader, or with reference to the orientation of the structure during nominal use, as appropriate. Similarly, the terms “inwardly” and “outwardly” generally refer to the orientation of a surface relative to its axis of elongation, or axis of rotation, as appropriate.

Similarly it should be appreciated that in the above description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment of this invention.

Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of this description.

Thus, while there has been described what are believed to be the preferred embodiments of the invention, those skilled in the art will recognize that other and further modifications may be made thereto without departing from the spirit of the invention, and it is intended to claim all such changes and modifications as fall within the scope of the invention. For example, any formulas given above are merely representative of procedures that may be used. Functionality may be added or deleted from the block diagrams and operations may be interchanged among functional blocks. Steps may be added or deleted to methods described within the scope of the present invention.

It will be appreciated that an embodiment of the invention can consist essentially of features disclosed herein. Alternatively, an embodiment of the invention can consist of features disclosed herein. The invention illustratively disclosed herein

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suitably may be practiced in the absence of any element which is not specifically disclosed herein.

The claims defining the invention are as follows:

1. A fixation device for a graft, the device comprising:
an elongate body having a first end and a second end;
a transverse passage for retaining a graft retainer element;
a first aperture located in the first end, and a second aperture
in the second end;
the first aperture and second aperture defining respective
ends of a longitudinal through path; and
a suture having a stop abutting the first end of the elongate
body.
2. The device according to claim 1, wherein the body has a
lower protruding portion located below the transverse pas-
sage.
3. The device according to claim 2, wherein the lower
protruding portion is a transverse smooth bulged portion with
a width that extends at least the longitudinal span of the
transverse passage.
4. The device according to claim 2, wherein the transverse
passage is defined as a channel being open to an upper surface
of the device.
5. The device according to claim 4, wherein a lower portion
of the channel extends toward the first end.
6. The device according to claim 5, wherein the channel has
an hook or 'L' shaped profile.
7. The device according to claim 2, wherein the transverse
passage is by a closed through aperture.
8. The device according to claim 5, wherein the body
tapers-down toward the second end.
9. The device according to claim 5, wherein the body tapers
down from a central region toward both the first end and the
second end.
10. The device according to claim 5, the device further
including the graft retainer element in the form of a closed
loop element located in the transverse passage for retaining
the graft with respect to the device.
11. The device according to claim 10, wherein the first
aperture and the second aperture are located proximal to the
centre of the respective first end and second end; and the
longitudinal through path is sized to receive a length of suture.
12. The device according to claim 1, wherein the longitu-
dinal through path is intersected by the transverse passage.
13. The device according to claim 12, wherein the longi-
tudinal through path extends from the first aperture to a first
intermediate aperture proximal to the transverse passage, and
from a second intermediate aperture proximal to the trans-
verse passage to the second aperture.
14. The device according to claim 13, wherein the longi-
tudinal through path is defined by a first passage segment and
a second passage segment, each passage segment being sub-
stantially straight inwardly-upwardly through-passages
extending from a respective first end and second end.
15. The device according to claim 1, wherein the longitu-
dinal through path is an axially directed through passage.
16. A method of using a fixation device according to claim
1 for drawing a graft through a first tunnel defined in a first
bone, the method comprising the steps of:
 - (a) providing the fixation device;
 - (b) coupling the fixation device to a length of suture having
a stop abutting a first end of the fixation device;
 - (c) coupling the fixation device to a first end of the graft;
 - (d) applying tension to a leading portion of the length of
suture to cause the fixation device to draw the graft up
through the tunnel;
 - (e) applying tension to a leading portion of the length of
suture to cause the fixation device to exit the tunnel;

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- (f) applying tension to the leading edge and a trailing
portion of the length of suture to cause the fixation
device to rotate flat across the tunnel; and
- (g) applying tension to the trailing portion of the length of
suture to thereby extract the length of suture from the
fixation device.
17. The method of claim 16, wherein the step (d) further
includes:
 - applying tension to a leading portion of the length of the
suture to cause the fixation device to draw the graft up
through the tunnel, such that the first end of the fixation
device is a trailing end as the fixation device is drawn up
through the tunnel, with the stop of the suture abutting
the trailing end.
18. A fixation device for a graft, the device comprising:
an elongate body having a first end and a second end;
a transverse passage for retaining a graft retainer element,
the body having a lower protruding portion located
below the transverse passage, wherein the lower pro-
truding portion has a width that extends at least the
longitudinal span of the transverse passage;
a first aperture located in the first end, and a second aperture
in the second end; and
the first aperture and second aperture defining respective
ends of a longitudinal through path.
19. A fixation device for a graft, the device comprising:
an elongate body having a first end and a second end;
a transverse passage for retaining a graft retainer element;
a first aperture located in the first end, and a second aperture
in the second end;
the first aperture and second aperture defining respective
ends of a longitudinal through path;
a suture extending through the longitudinal through path;
and
a graft retainer element extending through the transverse
passage.
20. The fixation device of claim 19, wherein the graft
retainer element is a closed loop.
21. A fixation device for a graft, the device including:
an elongate body having a first end and a second end;
a transverse passage for retaining a graft retainer element,
the elongate body having a lower protruding portion
located below the transverse passage, wherein the lower
protruding portion has a width that extends at least the
longitudinal span of the transverse passage;
a first aperture located in the first end, and a second aperture
in the second end;
the first aperture and second aperture defining respective
ends of a longitudinal through path;
a suture having a stop abutting the first end of the elongate
body, the suture extending through the longitudinal
through path; and
a graft retainer element being separate from the suture and
extending through the transverse passage, the graft
retainer element formed as a closed loop.
22. A fixation device for a graft, the device comprising:
an elongate body having a first end and a second end;
a transverse passage;
a first aperture located in the first end, and a second aperture
located in the second end;
the first aperture and second aperture defining respective
ends of a longitudinal through path;
a graft retainer element retained within the transverse pas-
sage;
a length of suture threaded through the longitudinal
through path having a stop abutting one of the first end or
second end of the elongate body; and

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a lower protruding portion located below the transverse passage and sized to locate the fixation device about a bone tunnel;

wherein the graft retainer element is in the form of a closed loop element.

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23. The device of claim **22** wherein the stop in the length of suture is a knot.

24. The device of claim **22** wherein the length of suture having a stop abutting one of the first end or second end of the elongate body is configured to enable a user to draw the device through a bone tunnel.

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